

## Kensey Nash

### 510(k) Summary

SEP 21 2007

**Submitted by:** Kensey Nash Corporation  
735 Pennsylvania Drive  
Exton, PA 19341

**Contact Person:** Jennifer J. Bosley, MBA, RAC  
Regulatory Affairs Specialist  
Ph: (484) 713-2100  
Fax: (484) 713-2903

**Date Prepared:** September 21, 2007

**510(k) #:** K072384

**Device Trade Name:** CopiOs® Bone Void Filler Sponge & Paste  
**Common/Usual Name:** Bone Void Filler  
**Proposed Classification:** Resorbable Calcium Salt Bone Void Filler Device  
21CFR § 888.3045  
Class II, MQV—87Orthopedics

#### Device Description:

CopiOs® Bone Void Fillers are resorbable sponges or paste (hydrated powder discs), which are manufactured from calcium phosphate and Type I bovine dermal collagen. CopiOs® devices are gamma-sterilized for single use and supplied in 1cc, 5cc and 10cc volumes.

#### Intended Use:

CopiOs® Bone Void Filler, in combination with autologous blood products such as bone marrow, is intended for use only for filling bone voids or gaps of the skeletal system (i.e. extremities, pelvis and spine, i.e., posterolateral spine fusion procedures with appropriate stabilizing hardware) that are not intrinsic to the stability of the bone structure. These voids may be a result of trauma or creation by surgeon. CopiOs Bone Void Filler is intended to be gently packed into the void or gap and will resorb during the course of the healing process.

#### Predicate Device:

K071237—CopiOs® Bone Void Filler Sponge & Paste (Kensey Nash Corporation)  
K033679—CopiOs™ Bone Void Filler (Centerpulse Spine Tech)

#### Substantial Equivalence:

CopiOs® Bone Void Filler Sponge & Paste is substantially equivalent to the legally marketed predicate device, CopiOs® Bone Void Filler Sponge & Paste (K071237) having identical device designs, materials, processing, intended use and fundamental scientific technology.

#### Non-Clinical Testing:

CopiOs® Bone Void Filler Sponge & Paste have previously undergone non-clinical testing, including animal study, biocompatibility, migration resistance, pH, hydration and handling characteristics. Testing provides reasonable assurance of safety and effectiveness for its intended use.

(484) 713-2100

KENSEY NASH CORPORATION, 735 PENNSYLVANIA DRIVE, EXTON, PA 19341



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 21 2007

Kensey Nash Corporation  
% Ms. Jennifer J. Bosley, MBA, RAC  
Regulatory Affairs Specialist  
735 Pennsylvania Drive  
Exton, PA 19341

Re: K072384

Trade/Device Name: CopiOs® Bone Void Filler Sponge & Paste  
Regulation Number: 21 CFR 888.3045  
Regulation Name: Resorbable calcium salt bone void filler device  
Regulatory Class: II  
Product Codes: MQV  
Dated: August 23, 2007  
Received: August 24, 2007

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.T

Page 2 – Ms. Jennifer J. Bosley, MBA, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devicesd  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications For Use Statement

510(k) Number (if known): K072384

Device Name: CopiOs® Bone Void Filler

### Indications For Use:

CopiOs® Bone Void Filler, in combination with autologous blood products such as bone marrow, is intended for use only for filling bone voids or gaps of the skeletal system (i.e. extremities, pelvis and spine, i.e., posterolateral spine fusion procedures with appropriate stabilizing hardware) that are not intrinsic to the stability of the bone structure. These voids may be a result of trauma or creation by surgeon. CopiOs Bone Void Filler is intended to be gently packed into the void or gap and will resorb during the course of the healing process.

Prescription Use   X   AND/OR Over-The-Counter Use         
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number           K072384